THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 29

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PAUL C. ANDERSON and KENNETH A. HIBBERD

Application 07/947,249¹

ON BRIEF

Before WINTERS, ROBINSON and SCHEINER, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

¹ Application for patent filed September 18, 1992. According to appellants, this application is a continuation of application 07/592,420, filed October 3, 1990, now U.S. Patent No. 5,304,732, which is a continuation of application 06/900,960, filed August 28, 1986, now abandoned, which is a continuation-in-part of application 06/639,321, filed August 10, 1984, now U.S. Patent No. 4,761,373, which is a continuation-in-part of application 06/586,802, filed March 6, 1984, now abandoned.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 203 through 266, all the claims pending in the application. Claims 232 through 234, and 264 are representative of the subject matter on appeal and read as follows:

- 232. A monocotyledonous seed from which a plant can be grown, the growth of which plant is resistant to inhibition by an herbicide at levels which normally inhibit the growth of that species of plant by inhibiting the activity of acetohydroxyacid synthase, wherein said resistance is conferred by an altered acetohydroxyacid synthase whose activity is resistant to inhibition by said herbicide at levels of said herbicide which normally inhibit the activity of an unaltered acetohydroxyacid synthase, and wherein the plant is of a species in which fertile plants can be regenerated from tissue culture.
 - 233. A seed according to claim 232, wherein the plant is a cereal.
- 234. A seed according to claim 232, wherein the plant is selected from the group consisting of rice, wheat, barley, sorghum, oats, rye and millet.
- 264. A monocotyledonous plant, the growth of which is resistant to inhibition by an herbicide at levels which normally inhibit the growth of that species of plant by inhibiting the activity of acetohydroxyacid synthase, wherein said resistance is conferred by an altered acetohydroxyacid synthase whose activity is resistant to inhibition by said herbicide at levels of said herbicide which normally inhibit the activity of an unaltered acetohydroxyacid synthase, and wherein the plant is of a species in which fertile plants can be regenerated from tissue culture.

All of the claims on appeal stand rejected under the first paragraph of 35 U.S.C. § 112, as "the disclosure is enabling only for claims limited to <u>Zea mays</u> (i.e. maize, or corn)." Examiner's Answer, page 3. We REVERSE the rejection.

DISCUSSION

In its broadest aspect, the claimed invention is directed to monocotyledonous seeds and plants resistant to herbicides that inhibit the activity of acetohydroxyacid synthase (AHAS), wherein resistance is conferred by an inheritable mutant AHAS. The examiner concludes that the claimed invention is not enabled throughout its scope, based on an analysis in keeping with that described in <u>In re Wands</u>, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988):

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte
Forman [230 USPQ 546, 547 (BdPatAppInt 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims (footnote omitted).

The examiner notes that the claims are extremely broad in that monocotyledons comprise a large and diverse group of plants, but maize is the only one represented in the working examples. In addition, the examiner estimates that "even if optimal culture conditions were already known for a given species, it would require 1 to 2 years to select a resistant cell line, regenerate plants, determine if the plants were herbicide resistant and fertile, and determine if the resistance trait was transmissible to the next generation," thus

"[t]he process disclosed in the specification requires a considerable amount of experimentation." Examiner's Answer, pages 7 and 8.

Ultimately, the examiner focuses on "[t]he unpredictable nature of the art [as] the most important factor in the instant application." Examiner's Answer, pages 4 and 5. For example, the examiner argues that one "can not predict the length of time necessary to select herbicide resistant cell lines . . . because of the random nature of mutagenesis . . . [t]he length of time is important because [it] affects the ability of cultured tissues to regenerate fertile plants." Although "it is a statistical certainty that the desired mutation will ultimately arise," the examiner maintains that "it is not certain that the cell culture technique will allow selection and isolation of cells harboring said mutation." Additionally, the examiner relies on Reisch² to establish that "cultured maize tissue is more cytogenetically stable than other monocotyledons, particularly rice and oat," thus, "it is easier to regenerate normal corn plants from culture than normal plants of other species." Examiner's Answer, page 7.

For these reasons, the examiner concludes that "it would require undue experimentation to make the claimed plants and seeds" (Examiner's Answer, page 8). If we can summarize the basis of the examiner's position, it is that it would require a considerable amount of experimentation, over an uncertain period of time, to develop

² B. Reisch, "Genetic Variability in Regenerated Plants," in <u>Handbook of Plant Cell Culture</u>, Volume 1, D.A. Evans et al, eds., Macmillan Publishing Co, New York, NY, pp. 748-769 (1983).

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monocotyledons, other than maize, exhibiting the required herbicide resistance, with no guarantee of success.

We accept, for the sake of argument, that obtaining the claimed seeds and plants by the processes disclosed in the specification might be more time consuming, or less consistent, for some monocotyledons than for maize (although there is no evidence of record that maize is not reasonably representative of monocotyledons in general).

Nevertheless, the examiner does not question the ability of one skilled in the art to follow the disclosed processes, nor rely on any evidence which would allow one to conclude that following the processes would be considered "undue experimentation" by one skilled in the art.

As explained in <u>PPG Indus., Inc. v. Guardian Indus. Corp.</u>, 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996), undue experimentation has little to do with the quantity of experimentation; it is much more a function of the amount of guidance or direction provided:

In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. See, e.g., In re Goodman, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); In re Vaeck, 947 F.2d at 496, 20 USPQ 2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some

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experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive." Atlas Powder Co. v. E.I. DuPont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex parte Jackson, 217 USPQ 804, 807 (1982).

Having reviewed the specification, including the working examples, in light of the examiner's commentary in the Answer, and appellants' commentary on pages 2 through 14 of the Reply Brief, we are satisfied that the specification provides reasonable guidance for one skilled in the art to make herbicide resistant monocotyledons, in addition to maize, and that the experimentation necessary, while considerable, would not be undue. Finally, to the extent that the examiner requires an assurance of certainty to demonstrate enablement, we note that no legal authority has been cited in support of this requirement. On the contrary, a requirement for certainty would be incompatible with any experimentation at all.

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We hold that the examiner has not set forth a reasonable basis for questioning the enablement of the claims on appeal. Accordingly, the rejection of the claims under 35 U.S.C. § 112, first paragraph, is reversed.

REVERSED

Sherman D. Winters Administrative Patent Judge)))
Douglas Robinson Administrative Patent Judge)) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES
Toni R. Scheiner Administrative Patent Judge)))

Appeal No. 1996-0963 Application 07/947,249

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